From: Smith, Michael (CBER)
Sent: Thursday, July 15, 2021 4:09 PM
To: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: STN 125742.0: IR RE the Pharmacovigilance Plan

Elisa,

The review team provided me with the below response regarding the request for an updated PVP.

Please submit the updated PVP for the Pfizer-BioNTech COVID-19 Vaccine to the BLA (BLA 125742) and EUA (EUA 27034) to include the risk of myocarditis or pericarditis. FDA acknowledges your efforts to assess ways to further evaluate the risk of myocarditis or pericarditis. However, in the interim, please provide an updated PVP by July 29, 2021; your PVP can be updated later as needed to align with your proposed strategy for evaluating this risk.

Regards,

Mike

- Please confirm receipt of this e-mail and let us know if you have any questions.

From: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
Sent: Wednesday, July 14, 2021 1:18 PM
To: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>
Subject: [EXTERNAL] RE: STN 125742.0: IR RE the Pharmacovigilance Plan

Hi Mike,

We do have a couple follow up questions to your request.

First, this is a request to update the PVP for the BLA (BLA 125742), we are assuming this request extends to the PVP for the EUA (EUA 27034; Pfizer-BioNTech COVID-19 Vaccine) as well? Please confirm, or if not, please clarify.

Second, I'm not sure how closely aware the reviewers of the BLA are of this but we are in process of assessing ways to further evaluate the risk of myocarditis or pericarditis associated with the Pfizer-BioNTech Vaccine. CBER asked for this on June 30, 2021 under BB-IND 19736. Please see CBER Comment 6 and the associated response in attached. This document was submitted to CBER under BB-IND 19736 on July 6, 2021 (SN 0397). As noted in the response, we plan to provide a proposal to CBER by August 2, 2021. Because we are still assessing we are not able to update the PVP by July 19. We propose to send the proposed PVP updates when we send the proposed strategy for evaluating this risk. Does CBER agree to this approach? Please advise.

Best regards,
Elisa

From: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>
Sent: Tuesday, July 13, 2021 3:31 PM
To: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>
Subject: [EXTERNAL] STN 125742.0: IR RE the Pharmacovigilance Plan

Elisa,

The review team has the below Information Request regarding the Pharmacovigilance Plan (PVP):

We note that myocarditis and pericarditis are not included in the PVP. However, the current EUA Fact Sheet includes Warnings for myocarditis and pericarditis. Therefore, please add myocarditis and pericarditis to the PVP as an important identified risk and submit a revised PVP as an amendment to BLA 125742 by July 19, 2021.

Regards,

Mike

- Please confirm receipt of this e-mail and let us know if you have any questions.

Mike Smith, Ph.D.
Captain, USPHS

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Food and Drug Administration
Center for Biologics Evaluation & Research
Office of Vaccines Research & Review
Division of Vaccines and Related Products Applications
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